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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,934	07/24/2003	Kenneth David Reginald Setchell	CHM-013M1	9470

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 HASSE & NESBITT LLC  
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 CINCINNATI, OH 45249

EXAMINER
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CHUNG, SUSANNAH LEE

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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11/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/625,934

Applicant(s)

SETCHELL ET AL.

Examiner

Susannah Chung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4, 5, 12-19, 44, 45, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 12-19, 44, 45, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20071024</u>                             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                           |

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### **DETAILED ACTION**

Claims 1, 2, 4, 5, 12-19, 44, 45, 50, and 51 are pending in the instant application. Claims 3, 6-11, 20-43, and 46-49 are canceled.

### ***Response***

The instant claims were previously rejected under 35 U.S.C. 103(a), 35 U.S.C. 112, 1<sup>st</sup> paragraph for written description and enablement rejections. The 103 rejection was withdrawn in the previous office action in view of Applicant's argument. The 103 rejection was based on well-established case law, which states that a stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties. (See *In re Anthony*, 162 USPQ 594, 596 (1969) and *In re Adamson*, 125 USPQ 233, 234 (1960)). Applicant argued that the equol in the prior art was not racemic and thus the case law did not apply. Examiner withdrew the 103 based on the assumption that the equol of the prior art was not racemic, but in reviewing the case history and state of the art, it appears that withdrawal of the 103 rejection was incorrect because the prior art equol could have been racemic. In addition, to the racemic issue, another issue is raised in terms of what the state of the art was at the time Applicants filed the instant claims. Prior art shows that the synthesis of s-equol was well known at the time and even available commercially. This action is to clarify the record. The following new rejections are made.

A telephone call was placed to Applicants representative Patrick Skacel to discuss the instant application on 10/24/2007.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

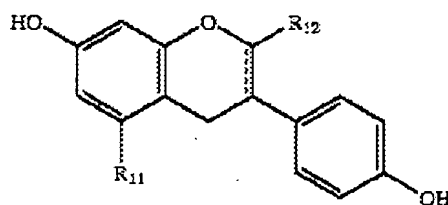
U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-5, 12-19, 44-45 and 50-51 are rejected under 35 U.S.C. 103(a) as obvious over Kelly et al., U.S. Pat. No. 6,455,032 ('032 Patent).

Applicant's instant elected invention teaches a compositions consisting essential of the S enantiomer of equol (S-equol).

Determination of the scope and content of the prior art (MPEP § 2141.01)



Kelly discloses compositions of formula, (See Claim 2, Column 17, Compound (10), approximately line 50.

Kelly discloses the racemic and enantiomers of equol. The method of preparing equol is in Column 8, starting approximately line 54, wherein the journal article Jaonnou et al., J. Steroid. Biochem. Molec. Biol., 54, 167-184 is incorporated by reference. In Jaonnou, on pages 169-170, the conversion of daidzein to equol by simple hydrogenation, hydrogenation and catalytic transfer

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hydrogenation are discussed. It is well known in the art that after hydrogenation of daidzein with a palladium catalyst that racemic equol will be the final product (See Lamberton et al, Aust. J. Chem., 1978, 31, 455-7, especially page 457, Experimental (b), last sentence, Merck Index, 1996, 12<sup>th</sup> Edition, page 3677, and (R,S)-Equol is commercially available from LC Laboratories and US Biological.) It is also well known in the art that equol's absolute configuration is S. (See Luk et al., J. Natural Products, 46(6), 852-861, especially page 853.) Kelly also discloses that the isomeric forms, keto-enol forms, and salts of the claimed compounds can be prepared according to methods well known in the art, such as described by Brown, W.H., Introduction to Organic Chemistry, 4<sup>th</sup> Edition, Brooks/Cole Pub. Co., California, (1988) (See Column 7, approximately line 34, of the '032 Patent).

Kelly discloses the compositions of equol can be used with a dermatologically acceptable carrier or formulated for oral administration (See Column 9, approximately line 15, '032 Patent). In claims 6, 7, 14, 15, and 19, compositions for application to the skin are taught.

Kelly discloses the compositions of equol may form conjugates such as  $\beta$ -(1,3)(1,6)-glucan (See claims 7, 14, and 15). It is well known in the art that isoflavones occur naturally in the soybean as various forms of  $\beta$ -glucosides. (See Setchell et al., Am. J. Clin. Nutr., 2002, 76, 447-53, especially page 447, column 2, approximately lines 20-21.) It is also well known that soy isoflavones circulate in several molecular forms, including glucuronide and sulfate conjugates. (See Shelnutt et al., Am. J. Clin. Nutr., 2002, 76, 588-94, especially page 588, column 2, approximately lines 15 and 16.)

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

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The difference between the prior art of Kelly and the instant claims is that in the prior art the racemic mixture of equol is preferred for use in dermatological compositions, while in the instant application, the s-enantiomer in food compositions is preferred.

*Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)*

However, in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with Kelly to make food compositions using an enantiomer or enantiomeric mixture of equol. A stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties not possessed by the racemic mixture. In re Anthony, 162 USPQ 594, 596 (1969) and In re Adamson, 125 USPQ 233, 234 (1960).

MPEP 2112 states the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 USC 102 or 103.

***Telephone Inquiry***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC



REBECCA ANDERSON  
PRIMARY EXAMINER

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Date: 29 October 2007